

**REMARKS**

***Status of the Claims***

Claims 1-3 are now present in this application. Claims 1-3 are independent. Claims 4-8 were previously canceled.

No claims are being amended, added or canceled in the present Reply.

Reconsideration of this application is respectfully requested based on the following remarks.

***Rejections under 35 U.S.C. § 103(a)***

Claims 1-3 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over **Misaki ‘996** (U.S. Patent No. 4,765,996) in view of **Kwak ‘997** (U.S. Patent No. 6,402,997), **Nanbu ‘675** (U.S. Patent No. 6,074,675) and **Tamaki ‘462** (U.S. Patent No. 6,436,462). Also, the reference of **WO ‘065** (WO 2008/140065) is provided as evidence. This rejection is respectfully traversed.

A complete discussion of the Examiner's rejection is set forth in the Office Action, and is not being repeated here.

**The Present Invention and Its Advantages**

The present invention is directed to iron-enriched and vitamin-enriched rice or barley, wherein the rice grains or barley grains are coated with an emulsifying agent-coated iron salt composition (e.g., claims 1 and 3) or coated with a polyglycerol fatty acid ester (claim 2). Also, the pending claims recite that the iron salt has an average particle diameter of 0.05 to 0.8 µm

(claims 1 and 3) or the range of 0.05 to 0.5  $\mu\text{m}$  (claim 2). Further, as recited in claims 1 and 3, the emulsifying agent is an enzymatically decomposed lecithin.

The present invention achieves unexpectedly less loss of, for example, vitamins and minerals upon storage of the rice or barley.

#### U.S. Case Law

M.P.E.P. § 2143 sets forth the guidelines in determining obviousness. First, the Examiner has to take into account the factual inquiries set forth in *Graham v. John Deere*, 383 U.S. 1, 17, 148 USPQ 459, 467 (1966), which has provided the controlling framework for an obviousness analysis. The four *Graham* factors are: determining the scope and content of the prior art; ascertaining the differences between the prior art and the claims that are at issue; resolving the level of ordinary skill in the pertinent art; and evaluating any evidence of secondary considerations (e.g., unexpected results). 383 U.S. 1, 17, 148 USPQ 459, 467 (1966). Second, the Examiner has to provide some rationale for determining obviousness, wherein M.P.E.P. § 2143 sets forth some rationales that were set established in the recent decision of *KSR Int'l Co. v Teleflex Inc.*, 550 U.S. 398, 82 USPQ2d 1385 (U.S. 2007).

Applicants respectfully submit that the *Graham* factors weigh in Applicants' favor, and that a proper rationale has not been set forth in forming the outstanding rejection.

#### The Present Invention is Patentable

To address the *Graham* factor of evaluating any evidence of secondary considerations, Applicants previously submitted a Declaration pursuant to 37 C.F.R. § 1.132 by co-inventor

Noboru SAKAGUCHI. In the Rule 132 Declaration, four different examples were prepared (i.e., “Enriched Rice 1-4”). In the previously submitted Rule 132 Declaration, four examples were prepared as follows:

- “Enriched Rice 1” (comparative example) was prepared in accordance with Example 5 of Misaki ‘996;
- “Enriched Rice 2” (the present invention) was prepared in accordance with Example 5 of Misaki ‘996 except the aqueous suspension containing ferric pyrophosphate was replaced with an emulsifying agent-coated iron salt composition as described in Example 1 of Applicants’ specification;
- “Enriched Rice 3” (comparative example) was prepared in the same way as Example 8 of Applicants’ specification, but carried out using the vitamins and minerals according to Example 5 of Misaki ‘996 (using the aqueous suspension containing ferric pyrophosphate);
- “Enriched Rice 4” (the present invention) was prepared in the same way as Enriched Rice 3 except the aqueous suspension containing ferric pyrophosphate of Misaki ‘996 was replaced with an emulsifying agent-coated iron salt composition as described in Example 1 of Applicants’ specification.

The following was measured: (1) residual ratio (%) of vitamins and minerals in the product, which is the finally prepared enriched rice (see Table I); (2) the percentage (%) of loss after washing the enriched rice (see Table II); and (3) residual ratio (%) after a one-month storage of the product (see Table III).

In the previous responses (e.g., the response dated March 30, 2010), Applicants also explained that **Table I** clearly showed that Enriched Rice products **2** and **4** (representing the present invention that utilizes an emulsifying agent-coated iron salt composition) have higher content of vitamins and iron, versus the comparative examples (Enriched Rice products **1** and **3**) (representing Misaki '996 that uses an aqueous suspension containing ferric pyrophosphate). For instance, Enriched Rice **2** has a significantly higher residual ratio of 69.0% versus the 29.8% of Enriched Rice **1**. Applicants also explained that **Tables II** and **III** showed unexpected results for the present invention (e.g., less vitamins and minerals are lost upon washing the rice with the present invention in **Table II**; have higher residual ratios (%) of vitamins and minerals in **Table III**).

However, in the outstanding Office Action, the Examiner states at pages 7-8:

In response, the declaration has been considered, and in regard to the rejection of record, the experimental results offered in applicants' 37 C.F.R. 132 affidavit:

1) does not clearly provide specific data about the specific components or quantities of each and every composition used in the comparison, and therefore lacks

comparative test data, because precisely what was done should be recited in the declaration: the actual steps carried out, the materials employed, and the results obtained should be spelled out. Nothing concerning the work relied upon should be left to conjecture or investigate;

2) does not provide a description of precisely what was tested: a) the invention as claimed; and b) the closest prior art, and therefore lacks technical description;

3) repeatedly discusses the results of washing the rice, however the claim is toward a product, not a method of washing, or the properties of the rice composition after it has been washed, and therefore is not commensurate with the scope of the claimed limitations;

4) does not appear to make a direct comparison between the claimed invention and the closest prior art, because the closest prior art has been relied on for each and every example; and

5) there is not a reasonable showing of statistical data that would conclude the experiment is factual as apposed to an occasional abnormality.

Applicants thank the Examiner for explaining her concerns regarding the previous Declaration. In response, Applicants herein submit another Rule 132 Declaration which is essentially a modification of the previously submitted Declaration, except containing more details to address the Examiner's comments. The attached Rule 132 Declaration addresses all five points by the Examiner.

Regarding the Examiner's point 1) above, the previous Rule 132 Declaration clearly explains that for, e.g., **Enriched Rice 1**, the same procedure as Example 5 of Misaki '996 was carried out to give the rice product (see page 2 of previous Declaration). One of ordinary skill in the art can simply read Misaki '996 for more information. **Enriched Rice 2 and 4** are made

pursuant to Example 1 of Applicants' specification. The skilled artisan could simply read the present specification for guidance. In any event, Applicants respectfully refer the Examiner to starting on page 3 of the herein attached Rule 132 Declaration ("Detailed Procedures for Preparation ..."). A detailed technical description of the materials employed, amounts thereof, testing conditions, etc. has been provided. For instance, the detailed preparation of **Enriched Rice 1** is described at pages 4-5 of the attached Declaration.

Regarding point 2), Applicants respectfully refer the Examiner to pages 8-10 of the new Declaration. Applicants note that there is a more detailed description at pages 8-10 of the attached Declaration versus the corresponding pages of the previous Declaration (e.g., 1 g of rice was mixed with 200 g of polished rice is described at page 9, section 2. of the attached Declaration)

Regarding point 3), Applicants respectfully submit that the declaratory evidence properly shows unexpected results for the claimed invention. The rice or barley of the present invention effectively suppresses the loss of vitamins and minerals due to washing with water by utilizing an iron salt coated on the surface thereof. An evaluation of these effects due to the washing of rice is provided in the attached Rule 132 Declaration. Applicants respectfully submit that unexpected results can still be shown for the claimed product. Specifically, the use of the product shows less loss of vitamins and minerals. The step of washing of the claimed product shows that the product achieves such advantages.

Further, regarding the Examiner's point 4), Applicant respectfully remind the Examiner that the comparative showing need not compare the claimed invention with all of the cited prior art, *In re Fenn et al.*, 208 USPQ 470 (CCPA 1981), but only with the closest prior art. *In re*

*Holladay*, 199 USPQ 516 (CCPA 1978). Further, U.S. case law states that a patent applicant may compare the claimed invention with prior art that is closer to the invention than the prior art relied upon by the Examiner. *See In re Holladay*, 584 F.2d 384, 199 USPQ 516 (CCPA 1978).

Here, Applicants respectfully submit that the superior effects by using an emulsifying agent-coated iron salt composition recited in claim 1 can be properly shown by comparing **Enriched Rice 1** with **Enriched Rice 2**, and **Enriched Rice 3** with **Enriched Rice 4**. After all, same procedure as Example 5 of Misaki '996 was carried out to give the rice products. Based on the declaratory evidence, one of ordinary skill in the art can make the proper comparisons, and understand the meaning and reasonableness of such comparisons. The skilled artisan would understand that the present invention achieves a higher content of vitamins and iron; significantly higher residual ratios of vitamins and minerals; and less vitamins and minerals are lost upon washing the rice.

Regarding the Examiner's point 5), Applicants respectfully submit the factual data in the Declaration(s) address this point. The skilled artisan would conclude that the comparisons of **Enriched Rice 1** to **Enriched Rice 2**, and **Enriched Rice 3** to **Enriched Rice 4**, show superior and unexpected results for the present invention.

Thus, it is believed that items 1)-5) of the Examiner's comments (reproduced above) are thus sufficiently addressed.

Applicants also believe that the skilled artisan would not combine the references as cited for reasons of record. The further citation of Tamaki '462 and WO '065 does not make the initial combination of Misaki '996, Kwak '997 and Nanbu '675 any more proper for reasons of record.

Regarding the newly cited reference of WO '065 as evidence, while enzymatically decomposed lecithin is also known as lysolecithin, WO '065 is a publication that is after the priority date of the present application. Thus, any assertion that enzymatically decomposed lecithin "inherently provide(s) improved hydrophilicity" is an *ex-post facto* analysis. The citation of WO '065 is improper.

Regarding Tamaki '462, the Examiner asserts "Tamaki teaches methods of making rice compositions that include iron salts, ..." (page 5 of the Office Action). However, Applicants respectfully submit that this is not the case, as Tamaki '462 does not disclose any composition that includes iron salts. Furthermore, though lysolecithin is disclosed, it is merely one of many listed additives, and the object of using the additives is to improve resistance to staling (see column 5, line 36 of the reference). The staling, however, means the staling of boiled rice (see column 1, lines 22-25 of Tamaki '462). This goal/objective of Tamaki '462 is not related to the present invention. Thus, one of ordinary skill in the art would not have the proper reason or rationale (e.g., motivation) to use lysolecithin to coat the iron salt as a solution to solving the problems in the art, wherein the present invention solves such problems. The references are improperly combined.

Reconsideration and allowance thereof are respectfully requested.

### ***Conclusion***

All of the stated grounds of rejection have been properly traversed, accommodated, or rendered moot. Applicants therefore respectfully request that the Examiner reconsider all presently outstanding rejections and that they be withdrawn. It is believed that a full and



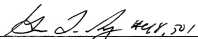
complete response has been made to the outstanding Office Action, and as such, the present application is in condition for allowance.

Should there be any outstanding matters that need to be resolved in the present application, the Examiner is respectfully requested to contact Eugene T. Perez, Registration No. 48,501, at the telephone number of the undersigned below to conduct an interview in an effort to expedite prosecution in connection with the present application.

If necessary, the Director is hereby authorized in this, concurrent, and future replies to charge any fees required during the pendency of the above-identified application or credit any overpayment to Deposit Account No. 02-2448.

Dated: September 27, 2010

Respectfully submitted,

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Attachment: Declaration under 37 C.F.R. § 1.132